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John G. Babish

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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT

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NOTIFICATION DATE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mweipdocket@mwe.com

DETAILED ACTION

This office action is in response to applicant's response filed on 12/09/2010.

Currently, claims 4-7 are pending.

The rejection of claims 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91-92, 97-101, 105-106, 108-109 of copending Application 11/344555; over claims 51, 116, 118-130 of copending application 11/344557; as being unpatentable over claims of 35-36, 40, 43-46 of copending application 11/403034; as being unpatentable over claims 1, 39, 40-41 of 10/464,834; as being unpatentable over claims 52-53 of copending application 11/344,561; as being unpatentable over claims 1-2, 4, 6-7, 11-15 of copending application 10/789,817, in view of Kuhrts (US 2003/0091656) is herein withdrawn. Note that applicant has filed terminal disclaimers. Application 11/344,557 has been abandoned.

The rejection of Claims 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of 7,431,948, in view of Kuhrts (US 2003/0091656, see page 3, paragraph [0024]) is herein withdrawn. Note that applicant has filed terminal disclaimers.

The rejection of Claims 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending Application No. 10/590,424 is MAINTAINED. Note: TD filed by the applicant was disapproved by the office.

The rejection of Claims 4-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 250-256 of copending application 10/532,388; as being unpatentable over claims 1, 8, 13-14, 18-27, 152-153 of copending Application No. 10/464410, in view of Kuhrts (US 2003/0091656, see page 3, paragraph [0024]) is MAINTAINED. Note: TD's filed by the applicant were disapproved by the office.

The rejection of Claims 4-7 under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (WO 03/035007, PTO-892) is MAINTAINED. See under response to arguments.

The rejection of claims 4-7 under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (WO 2004/037180, PTO-892) is MAINTAINED. See under response to arguments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to claims 4, and 7 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for the limitation, "a composition comprising a reduced isoalpa acid (RIAA) and isoalpa acid (IAA) derived from hops wherein the RIAA and IAA are in a synergistic ratio of about 3:1 to about 1:10.....wherein the composition has a combination index (CI) of RIAA and IAA of less than 1". The original specification merely discloses composition having a combination index (CI) of RIAA and IAA of less than 1 at particular ratios such as 10:1, 3:1, 3:2, 1:1, 2:3, 1:10 at particular amounts of RIAA and IAA and not at any ratios of RIAA:IAA between 10:1 to about 1:10. See Figures 4A-F.

Any claim containing a limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. See MPEP § 2163- § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (WO 03/035007, PTO-892 of record).

Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one compound isolated or derived from hops. The compounds isolated or derived from hops include isoalpha acids, and reduced isoalpha acids which include isohumulone, isoprehumulone, dihydro-isohumulone, tetrahydroisohumulone. See abstract; page 7, TABLE 2; page 10, lines 6-10; page 11, EXAMPLE 1; page 24, claims. The compositions therein can contain about 0.05 to about 1 wt % of compounds isolated or derived from hops. See page 8, lines 23-25.

Babish et al. does not expressly teach a method of treating inflammation comprising administering a combination of isohumulone, and dihydro-isohumulone, and the particular ratio of reduced isohumulone : dihydro-isohumulone as about 10:1 to about 1:10, in the composition.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ isohumulone, and dihydro-isohumulone in the method of treating inflammation because Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one compound isolated or derived from hops which include isohumulone, and dihydro-isohumulone. It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e is to treat inflammation, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Babish et al., the instant claims contain two compounds used for

treatment of inflammation. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpa acid and isoalpa acid, to obtain a desired effect such as reducing inflammation.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpa acid employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of reduced isoalpa acid : isoalpa acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding the recitation “wherein the composition has a combination index (CI) of RIAA and IAA of less than 1”, since Babish et al. renders the administration of claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the combination index (CI), are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are

also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01.

Response to Arguments

Applicant argues that “WO 03/035007 discloses the anti-inflammatory properties of the hops derived compounds in combination with curcuminoids. WO 03/035007 does not provide any teaching or suggestion that a combination of IAA and RIAA (as claimed) could have synergistic properties in treating inflammation. Therefore, WO 03/035007, in effect provides a vast number of compounds that could potentially be used in place of curcuminoids in combination with the hop derived compounds in that reference.” These arguments have been considered but not found persuasive. Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one compound isolated or derived from hops such as isohumulone, isoprehumulone, dihydro-isohumulone, tetrahydroisohumulone. Babish et al. also teach isohumulone, isoprehumulone, dihydro-isohumulone as the preferred compounds in the method of treating inflammation. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to combine isohumulone, and dihydro-isohumulone in the method of treating inflammation, since both are known to treat inflammation. It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e is to treat inflammation, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in

the prior art. As shown by recited teachings of Babish et al., the instant claims contain two compounds used for treatment of inflammation. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). Applicant's unexpected results i.e synergistic properties have been considered, it is pointed out that these synergistic properties only hold at certain ratios of RIAA and IAA at particular amounts, and not at any amounts as in instant claims.

Applicant argues that "Applicants have unexpectedly discovered that it was only in these ratios and amounts, which resulted in synergy, that the claimed compounds were also suitable for producing commercial viable products for reducing inflammation. See Example 4 and the shaded area in Figure 4A-4H." Applicant's unexpected results i.e synergistic properties have been considered, it is pointed out that these synergistic properties only hold at certain ratios of RIAA and IAA at particular amounts, and not at any amounts as in instant claims. Synergy was noted at the lower portion of the dose-response curves for RIAA:IAA combinations of 10:1, 1:1 and 1:100, covering RIAA concentration of 2.5×10^{-8} to 0.26 $\mu\text{g/mL}$ i.e at less than 0.1 % of RIAA and IAA individually, and synergy was noted at the higher end of the dose-response curve for RIAA:IAA, ratios of 100:1, 3:1, 3:2, 2:3 and 1:10 over RIAA concentration of 0.31 to 68,261 $\mu\text{g/mL}$ i.e synergy is observed at only particular/specific doses, and not at any dose/amount of RIAA and IAA. It is pointed out that synergy is not observed for RIAA:IAA combinations of 1:1 wherein RIAA and IAA individually comprise at least 0.1 % of the composition i.e synergy is not observed at all the ratios of 3:1 to 1:10 wherein RIAA and IAA individually comprise at least 0.1 % of the composition. Thus, the

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evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed method. See MPEP § 716.02(d). Further, RIAA employed is Redihop (rho-iso-alpha acids(RIAA), 29.5-30.5 %, <0.2 % iso-alpha acids) see page 27, paragraph [093], thus all of the specific compounds claimed in claim 4 are not those in which specifically demonstrated synergy in Table 6. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art commensurate in scope because Babish et al. teach isohumulone, isoprehumulone, dihydro-isohumulone as the preferred compounds in the method of treating inflammation. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to combine isohumulone, and dihydro-isohumulone in the method of treating inflammation, since both are known to treat inflammation.

Further, instant claim 4 recites the employment of reduced isoalpha acid (RIAA) which can include tetra-hydroalpha acids and hexa-hydroalpha acids which are also reduced isoalpha acids i.e obtained by reducing isoalpha acids. Applicant has not provided any data for these reduced isoalpha acids.

Note: Applicant in paragraphs [035]-[036] recite that "tetra-hydroisoalpha acid" and "hexa-hydroisoalpha acid" refer to a certain class of reduced isoalpha acids i.e tetra-hydroalpha acids and hexa-hydroalpha acids are also reduced isoaplha acids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babish et al. (WO 2004/037180, PTO-892).

Babish et al. teaches a method of treating inflammation comprising administering a composition comprising at least one fraction isolated or derived from hops. The compounds in fractions isolated or derived from hops include isoalpha acids such as isohumulone, isocohumulone, isoadhumulone, and reduced isoalpha acids such as dihydro-isohumulone, dihydro-isocohumulone, dihydro-isoadhumulone. See abstract; page 16; page 85, EXAMPLE 3; page 88, Table 4; pages 103-105; claims. The compositions therein can contain about 0.001 to about 10 wt % of compounds isolated or derived from hops. See page 47, lines 22-24.

Babish et al. does not expressly teach a method of treating inflammation comprising administering a combination of isoalpha acids, and reduced isoalpha acids, and the particular ratio of reduced isoalpha acids : isoalpha acids as about 10:1 to about 1:10, in the method therein.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a combination of reduced isoalpha acids, and isoalpha acids in the method of treating inflammation because Babish et al. teaches a method of treating

inflammation comprising administering a composition comprising reduced isoalpha acids or isoalpha acids. It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e is to treat inflammation, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Babish et al., the instant claims contain two compounds reduced isoalpha acids, and isoalpha acids used for treatment of inflammation. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid, to obtain a desired effect such as reducing inflammation.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding the recitation “wherein the composition has a combination index (CI) of RIAA and IAA of less than 1”, since Babish et al. renders the administration of claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the combination index (CI), are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01.

Response to Arguments

Applicant’s arguments that “WO 2004/037180 is not a prior art reference for the purpose of this rejection” have been considered, but not found persuasive. It is pointed out that WO 2004/037180 was filed on 20 October 2003 (with different inventive entity such as inventors Darland Gary, Lerman Robert et al. i.e by another) before the filing date of the present application (i.e February 27, 2004), and qualifies as prior art under 102(e) and is used as prior art under 103 in the instant case. See MPEP 706.02(a), 706.02(f), 706.02(f)(1).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 250-256 of copending application 10/532,388; as being unpatentable over claims 1, 8, 13-14, 18-27, 152-153 of copending Application No. 10/464410, in view of Kuhrts (US 2003/0091656, see page 3, paragraph [0024]). Although the conflicting claims are not identical, they are obvious over each other. The above copending applications claim administration of reduced isoalpha acids in treating inflammation. It would have been obvious to a person of ordinary skill in the art at the time of invention to employ isoalpha acids such as isohumulone, isocohumulone, isoadhumulone, in the method of treating inflammation because Kuhrts teaches that isohumulone, isocohumulone, isoadhumulone are useful in treating inflammation. It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose i.e treating inflammation., in order to form a composition which is used for the very same purpose i.e treating inflammation. The idea for combining them flows logically from their having been used individually in the prior art. It would have

been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpa acid : isoalpa acid, to obtain a desired effect such as reducing inflammation. One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpa acid employed in the method of reducing inflammation in which the ratio of reduced isoalpa acid : isoalpa acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

NOTE: Applicant has filed Terminal disclaimers to obviate the obviousness-type double patenting rejections over applications 10/532,388, 10/464,410. The terminal disclaimers provided by the applicant have been disapproved by the office because the filing date for the application is incorrect.

Claims 4-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of copending Application No. 10/590,424. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims overlaps with the stated claims of 10/590,424. Note that, "A composition comprising a fraction isolated or derived from hops" in the copending applications

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implies that the pharmaceutical composition would contain isoalpha and reduced isoalpha acid. The claimed composition is within the scope of the claims of the copending Application 10/590,424. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpha acid : isoalpha acid, to obtain a desired effect.

This is a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

NOTE: Applicant has filed Terminal disclaimers to obviate the obviousness-type double patenting rejections over applications 10/590,424. The terminal disclaimers provided by the applicant have been disapproved by the office because the filing date for the application is incorrect.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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